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09/936,514	09/14/2001	Takeya Abe	018793-253	4410

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EXAMINER

FRONDA, CHRISTIAN L

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/936,514

Applicant(s)

ABE ET AL.

Examiner

Christian L. Fronda

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-16 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,9-16 and 25-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

1. Claims 1-3, 9-16, 25-31 are pending and under consideration in this Office Action.
2. The objection of the disclosure for lack of a statement that that indicates that the instant application is the US National Stage filing of PCT Application No. PCT/JP01/00313, filed 01/12/2001, which claims foreign priority under 35 U.S.C. 119(a)-(d) to foreign patent application 2000-7993 filed in Japan on 01/17/2000, has been withdrawn in view of applicants' amendment to the specification filed 07/25/2005.
3. The objection to claims 17-24 under 37 CFR 1.75 as being a substantial duplicate of claims 5-16 is moot in view of applicants' cancellation of claims 17-24 in the amendment filed 07/25/2005. This objection has been withdrawn.
4. The rejection of claims 1-24 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps and for being indefinite has been withdrawn in view of applicants amendments to the claims filed 07/25/2005.
5. Since the amendment filed 07/25/2005 cancels claims 4-8 and 17-24, the rejection of these claims under 35 U.S.C. 103(a) is moot and has been withdrawn.

### ***Claim Objections***

6. Claims 9-16 are objected to because the claims depend from cancelled claims 7 and 8. Appropriate correction is required.

### ***Claim Rejections - 35 U.S.C. § 112, 1st Paragraph***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-3, 9-16, 25-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments filed 07/25/2005, have been fully considered but they are not persuasive. Applicants' position is that the specification supports the claims under the written description requirement and that the claims do not require and do not make any reference to any organism. The Examiner respectfully disagrees for the reasons of record as supplemented below.

In the evaluation of the claims for compliance with the written description requirement of 35 U.S.C. 112, of particular relevance is 66 FR 1099, Friday, January 5, 2001, which states: "*Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because "it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed." (see p. 1100, 1<sup>st</sup> column, line 47 to 2<sup>nd</sup> column, line 2).

The amended claims are genus claims directed toward a method using a genus of nitrile hydratase of any amino acid sequence and structure from any microorganism fungus body. The scope of the claims includes many microorganisms and many nitrile hydratase enzymes with widely differing structural, chemical, and physical characteristics. Furthermore, the genus is highly variable because a significant number of structural differences between genus members exists.

The recitation of the name "nitrile hydratase" and its source as a microorganism fungus

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body do not define any structural features and amino acid sequences commonly possessed by the genus. Furthermore, the specification does not describe and define any structural features and amino acid sequences commonly possessed by the genus. As stated in the previous Office Action, the specification discloses a MT-10827 (FERM BP-5785) which is not a not a fungus, but is instead an *E.coli* host cell transformed with a plasmid containing a polynucleotide encoding a bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095 (see US Patent 5,910,4352), and its use in converting acylonitrile to its corresponding amide acylamide. However, the specification does not provide an amino acid sequence of the said bacterial nitrile hydratase from *Pseudonocardia thermophila* JCM3095, and fails to provide a written description of additional nitrile hydratase enzymes and microorganisms as encompassed by the claimed genus. Thus, one skilled in the art cannot visualize or recognize the identity of the members of the claimed genus.

The Court of Appeals for the Federal Circuit has recently held that a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definitions, such as the structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (Fed. Cir. 1997), quoting *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) (bracketed material in original). To fully describe the genus of genetic materials, which is a chemical compound, applicants must (1) fully describe at least one species of the claimed genus sufficient to represent said genus whereby a skilled artisan, in view of the prior art, could predict the structure of other species encompassed by the claimed genus and (2) identify the common characteristics of the claimed molecules, e.g. structure, physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or a combination of these. Therefore, the instant claims are not adequately described.

In view of the above considerations, one of skill in the art would not recognize that applicants were in possession of a genus of nitrile hydratase of any amino acid sequence and structure from any microorganism fungus body

### ***Claim Rejections - 35 U.S.C. § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in

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section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1-3, 9-16, 25-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oriel et al. (WO 99/55719; reference of record) in view of Chen. (J Biol Chem. 1967 Jan 25;242(2):173-81; reference of record). The reference teachings have been stated in the previous Office Actions.

Applicants' arguments filed 07/25/2005, have been fully considered but they are not persuasive. The Examiner respectfully disagrees with applicants' position that the references of record do not meet the requirements for a *prima facie* case of obviousness.

One of ordinary skill in the art at the time the invention was made would have been motivated to modify the process of Oriel et al. such that the amide solution is subjected to acid-charcoal treatment as taught by Chen for the purposes of having a simple and beneficial purification process that produces an amide compound and removes impurities including lipid impurities. Since the claims as amended do not recite a process step for removing protein, the references do not need to disclose this particular limitation which was not recited in the amended claims. Hence, the combination of the references teach and suggest all the limitations of the claimed invention.

Because the process steps of the modified process of Oriel et al. stated above are the same as the process steps of the claims, then the modified process of Oriel et al. stated above would inherently produce the amide compounds recited in the claims.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use organic acids of acrylic acid or methacrylic acid for the purpose of maintaining the desired pH of the solution (pH 3.5- pH 6.5) from which the amide compound is prepared since the acid dissociation exponent known in the art of acrylic acid is 4.25 and methacrylic acid is 4.66.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to maintain a temperature from 10 to 50°C for the purpose of optimizing the removal of impurities from the produced amide containing solution.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to set the liquid obtained by separating the activated charcoal at saturation temperature or lower for the purpose of optimizing precipitation and crystallization of the produced amide.

The Examiner has determined the scope and contents of the prior art, ascertained the differences between the prior art and the claims at issue, and found the claimed invention to have been obvious in light of the combined teachings of the references.

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*Conclusion*

11. No claims are allowed.

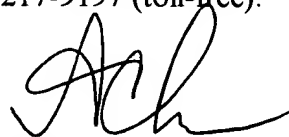
12. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

14. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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